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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,237	07/19/2001	Jeffrey B. Miller	08472-720003 / MGH-1176.2	9307
26161	7590	03/22/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			SULLIVAN, DANIEL M	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/909,237

Applicant(s)

MILLER, JEFFREY B.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 21-54 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 21-24, 49 and 52, drawn to an isolated skeletal muscle stem cell, classified in class 435, subclass 325.
- II. Claims 25-36, 39, 50 and 53, drawn to an isolated muscle stem cell that produces myoblasts, classified in class 435, subclass 325.
- III. Claims 37-48, 51 and 54, drawn to an isolated cardiac muscle stem cell, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to muscle stem cells having distinct properties (*i.e.*, a stem cell that produces a skeletal muscle cell *vs.* a stem cell that produces a myoblast *vs.* a stem cell that produces a cardiac muscle cell). The inventions are not disclosed as capable of use together and have different modes of operation, function and effect which provide for or are a consequence of their distinct phenotypic characteristics recited in the claims.

Examination of Groups II and III is further restricted to a single named exogenous nucleic acid sequence. Cells comprising exogenous nucleic sequences encoding each of the polypeptides set forth in claims 31 and 43 are distinct, each from the other, in expressing structurally and functionally unrelated polypeptides which provide unique properties to the cell.

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The cell of claims 27-28 or 39-40 is related to the cell of claims 29-31 or 41-43, respectively, in that they comprise subcombinations that are useable together (*i.e.*, the promoter sequence can be used with the coding sequence). The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the promoter can be used to express any nucleic acid, not just the protein coding nucleic acids of claims 29-31 or 41-43 and the protein coding sequences can be expressed from any promoter, not just the promoter sequence of claims 27-28 or 39-40. See MPEP § 806.05(d).

An Election to prosecute Group II should include election of either the cell comprising the stem cell active promoter of claims 27-28 or a single protein encoding sequence from claim 31.

An Election to prosecute Group III should include election of either the cell comprising the stem cell active promoter of claims 39-40 or a single protein encoding sequence from claim 43.

Claim 26 links the cell comprising a nucleic acid comprising a muscle stem-cell active promoter of claims 27-28, the cell comprising a nucleic acid encoding a marker protein of claims 29 and 31, and the cell comprising a nucleic acid encoding a cell surface polypeptide of claims 28 and 31.

Claim 38 links the cell comprising a nucleic acid comprising a muscle stem-cell active promoter of claims 39-40, the cell comprising a nucleic acid encoding a marker protein of claims 41 and 43 and the cell comprising a nucleic acid encoding a cell surface polypeptide of claims 42 and 43.

Claim 29 links the marker proteins of claim 31.

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Claim 30 links the cell surface polypeptides of claim 31.

Claim 41 links the marker proteins of claim 43.

Claim 42 links the cell surface polypeptides of claim 43.

The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Thus, if Group II is elected and claim 26 is deemed allowable, the subject matter of claims 27-31 will be rejoined and the linked inventions will be examined together. If claim 26 is not deemed allowable, examination will be restricted to the subject matter of claims 27-28, 29 or 30 depending upon the elected species. If claim 29 is examined and not deemed allowable, examination will be restricted to the species elected from claim 31. Likewise, if claim 30 is examined and not deemed allowable, examination will be restricted to the species elected from claim 31.

If Group III is elected and claim 38 is deemed allowable, the subject matter of claims 39-43 will be rejoined and the linked inventions will be examined together. If claim 38 is not deemed allowable, examination will be restricted to the subject matter of claims 39-40, 41 or 42 depending upon the elected species. If claim 41 is examined and not deemed allowable, examination will be restricted to the species elected from claim 43. Likewise, if claim 42 is examined and not deemed allowable, examination will be restricted to the species elected from claim 43.

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Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, or because each of the distinct Inventions comprise distinct elements and therefore cannot be searched coextensively, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER